

Federal Activities Related to Pregnancy and Lactation

An array of federal agencies support research, health care and clinical practice, communications, and collaborative efforts that are directly applicable to the HHS Task Force on Pregnant and Lactating women. Figure 1 lists federal agencies included in this report. Federal activities were identified by Task Force agencies, supplemented by systematic searches of agency databases, websites, and publications.

Research Activities

Each of the featured federal agencies offer unique contributions to research related to pregnancy and lactation. Agencies with a strong foundation in toxicology, maternal and fetal medicine, teratology, and epidemiology often collaborate to assess how prenatal exposures can affect risks to the offspring. Biomedical research agencies have taken a lead role in studying the safety and effectiveness of interventions for pregnant and lactating women and their children. Health care services agencies, along with their medical research counterparts, support efforts to measure the utilization, quality, and impact of health care services and interventions.

Prenatal Exposures

Identifying the impact of prenatal exposures is a shared research interest of several federal agencies. The National Toxicology Program (NTP) is an interagency program, involving NIH, EPA and others, that provides scientific information about hazardous substances in the environment and serves as a central resource for activities, programs, and policies that advocate for health and disease prevention. For example, one NTP-supported study examined the developmental effects and pregnancy outcomes associated with cancer chemotherapy use in pregnant women. At the FDA, researchers are evaluating prenatal exposure to hand-held metal detectors and MRIs. Through its epidemiological research, CDC addresses the impact of occupational and environmental exposures that affect the health of pregnant women and their offspring. Figure 2 lists examples of studies of prenatal exposure in military personnel and veterans.

Figure 2: Prenatal Exposure and the Military

Military personnel and veterans may be exposed to stresses and toxins not typically found in civilian life.

Examples of DoD and VA studies include:

- the effect of maternal PTSD on preterm birth (VA);
- environmental exposures for women who served in the Gulf War (DoD); and
- procedures for counseling female veterans about the teratogenic risks of prescription medications.

Figure 1: Federal Agencies

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Department of Agriculture (USDA)
- Department of Defense (DoD)
- Department of Veterans' Affairs (VA)
- Environmental Protection Agency (EPA)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- National Institutes of Health (NIH)
- National Vaccine Program Office (NVPO)
- Office of the Assistant Secretary for Health (OASH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

taken by pregnant women and possible links to birth defects.

Safety and Efficacy of Medicinal Therapies in Pregnant and Lactating Women

Several federal agencies support research that investigates the safety and efficacy of medications, therapies, vaccines, and other pharmaceutical drugs in pregnant and lactating women. As the federal regulatory agency with the responsibility for approval of drugs, devices, and biologics, FDA supports research to advance knowledge about the safety and efficacy of these products.

Research areas that involve pregnant and lactating women include basic research into mechanisms of therapies in pregnancy and lactation; medication use, safety, and efficacy in pregnant and lactating women; pharmacodynamic and pharmacokinetics; exposure to medical devices; preclinical studies in toxicity; and the effects of tobacco product use in pregnant and lactating populations. For example, FDA established the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP) -- a collaborative, multi-site research program that conducts studies of medication use and outcomes in pregnancy. USDA supports studies on the safety and effectiveness of

vitamin supplementation in pregnant women and young children. As shown in Figure 3, NIH has established state-of-the-art clinical research networks with specialized expertise in studies involving pregnant women.

A range of CDC programs, including the Center for Global Health, conduct research to improve pregnancy outcomes around the world. Research topic areas include antiretroviral therapies for HIV-positive pregnant women, influenza vaccines for pregnant women, and safety and efficacy of antiretroviral therapies in hepatitis B virus (HBV) and HBV-HIV infected women. The National Vaccine Program Office, part of the HHS Office of the Assistant Secretary for Health, directs clinical studies that focus on immunization of pregnant women. Examples include: 1) Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular pertussis vaccine (Tdap) Safety in Pregnant Women, and 2) Safety of Simultaneous Administration of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and Inactivated Influenza Vaccine in Pregnant women. In each study, reaction symptoms are observed and analyzed to determine maternal and fetal outcomes. With the most recent Zika outbreak, several federal agencies collaborated to develop and fund studies about maternal immunization and Zika infection in pregnant women.

Utilization and Quality of Care for Pregnant and Lactating Women

Some federal agencies are directly involved in providing medical care for pregnant and lactating women, and conduct their own research on utilization and quality of care as it relates to their programs. Other agencies do not provide health care services themselves, but as part of their research mission they collect data or conduct broad-based studies on the utilization and quality of care.

Figure 3: NIH Clinical Research Networks

The Obstetric-Fetal Pharmacology Units (OFPU) network provides the expert infrastructure needed to test therapeutic drugs during pregnancy. The OFPU allows researchers to conduct safe, technically sophisticated, and complex studies in pharmacology, placental transfer, placental biotransformation of drugs and therapeutics. The NIH's Maternal-Fetal Medicine Unit Network (MFMU) is a premier scientific research network with specialized clinical expertise in maternal-fetal medicine. The MFMU designs and implements rigorous randomized controlled clinical trials to decrease maternal, fetal, and infant morbidity related to maternal complications, fetal growth abnormality, and preterm; and to provide the basis for cost-effective, evidence-based obstetric practice. The International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Network is a collaboration of institutions, investigators, and others that evaluate potential therapies for HIV and HIV related symptoms in infants, children, adolescents, and pregnant women both domestically and internationally.

Although HRSA is not primarily a research agency, it supports research related to clinical care. HRSA research projects often focus on health care utilization, dissemination of evidence-based practices in the community, and the impact of HRSA's programs. For example, one HRSA study looked at the efficacy of an exercise intervention to prevent perinatal depression in women who attended federally qualified health centers. HRSA also supports the MCH Research Network on Pregnancy Related Care (also known as the CARN Network), a group of practicing obstetrician-gynecologists affiliated with the American College of Obstetricians and Gynecologists (ACOG). CARN conducts a range of provider surveys to inform clinical practice.

Researchers funded by the VA are assessing the coordination of pregnancy care received by women veterans. To evaluate these health services, researchers are examining health care utilization data and conducting interviews from women veterans and their health care providers.

Figure 4: Examples of Large Databases

- **Medical Expenditure Panel Survey (MEPS)** – contains information about the types of health services that Americans use, frequency of use, cost, and how services are paid. (AHRQ)
- **Healthcare Cost and Utilization Project (HCUP)** -- provides comprehensive hospital care data on in-patient stays, and emergency room, ambulatory surgery and service visits. (AHRQ)
- **Pregnancy Risk Assessment Monitoring System (PRAMS)** -- collects data about maternal attitudes and experiences before, during, and shortly after pregnancy. (CDC)
- **Maternity Practices in Infant Nutrition and Care (mPINC)** -- collects information about maternity practices related to breastfeeding from maternity care service facilities every two years. (CDC)

FDA, NIH, and AHRQ support research on medication use among pregnant and lactating women with various medical conditions like asthma, seizure disorders, mental health disorders, diabetes, and bacterial and viral infections. AHRQ's largest research portfolio relevant to pregnancy and lactation is devoted to the cost and quality of maternal and obstetric care. AHRQ conducts research on a range of topics like the risks and benefits of labor induction and cesarean section, implementation of recommended therapies, and differences across hospitals and providers in obstetric practice. CDC and AHRQ also provide funding for large databases with information about the use of medication and other interventions by pregnant women, as shown in Figure 4.

Several agencies support research on the utilization, acceptance, and benefits of maternal

immunization. For example, CDC is currently funding a study on immunization delivery in obstetrics and gynecology settings, to promote vaccination of women before and during pregnancy. CDC's Internet Panel Survey on Pregnant Women is conducted in November and April of each year to monitor vaccination trends in pregnant women, and includes topical questions on areas of special interest, such as Zika virus. NVPO's efforts to enhance maternal immunization research include developing a maternal-neonatal database and validating vaccine safety definitions in research involving pregnant women and newborns.

Health Care and Clinical Practice

Beyond supporting research efforts related to pregnancy and lactation, federal agencies contribute to health care and clinical practice in the forms of recommendations, guidance, and/or direct provision of clinical care. NIH, AHRQ, NVPO, OASH, CDC, and FDA do not directly support clinical care; however, each agency's research helps shape the scientific evidence base for clinical practice recommendations and efforts to inform both health professionals and the public.

In addition to their own research and clinical care activities, federal agencies advise other entities about the research and topic areas that each agency supports. NIH works with the American Congress of Obstetricians and Gynecologists (ACOG) to ensure that clinical practice guidelines that rely upon scientific evidence from NIH-funded studies are effectively translated for use in clinical practice. NVPO, through the National Vaccine Advisory Committee, helps develop recommendations for vaccine research priorities and ways to promote adequate availability of safe and effective vaccines. AHRQ and OASH, among others, create initiatives and recommendations to address the importance of healthy lifestyles while pregnant and breastfeeding. AHRQ works with OASH, HRSA, SAMHSA, and Ohio State University on the Healthier Pregnancy initiative to increase screening and referral for preventive services for tobacco use, alcohol use, depression, intimate partner violence, obesity and breastfeeding in pre- and perinatal care settings. AHRQ also sponsors the Evidence-Based Practice Reports which provides science-based information on costly, yet common, medical conditions and novel health care strategies and technologies. These reports, along with information provided by other federal agencies, help to form the basis of recommendations for the U.S. Preventative Services Task Force (see Figure 5).

Figure 5: U.S. Preventive Services Task Force (USPSTF)

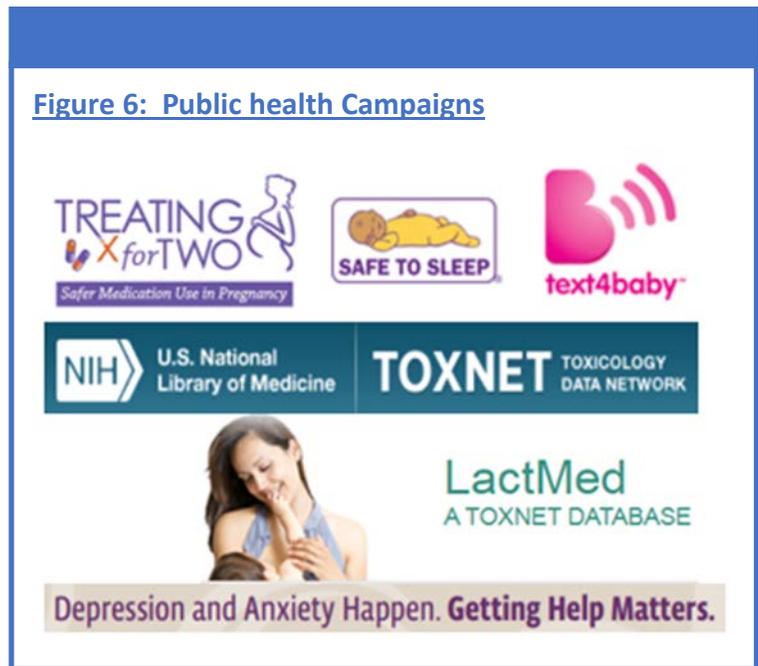
Led by AHRQ, USPSTF is a voluntary panel of experts who convene to provide evidence-based recommendations about clinical preventive services like preventive medications, vaccines, screenings, and counseling services. NIH and other federal agencies work with AHRQ on USPSTF recommendations. Eighteen of the current USPSTF recommendations are directly focused on pregnancy and/or lactation, and twenty-six recommendations are related to pregnancy and/or lactation.

FDA provides regulations and recommendations to ensure safety and effectiveness of therapies, prescription drugs, biologics, and medical devices for pregnant and lactating women. For example, the FDA offers vital information about toxicity potential of infectious disease therapies for women of childbearing age and pregnant women in the guidance *Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications*. FDA is also involved in training activities for healthcare providers to teach them about safety and effectiveness of certain drugs in pregnant women.

HRSA, DoD, and VA directly support clinical care through programs and health care services. HRSA's Health Center Program provides comprehensive primary care services to over 24 million people nationwide through a national network of health centers. HRSA also supports several programs that benefit pregnant women, infants, and children: Title V Maternal and Child Health Block Grant, Healthy Start, Maternal, Infant, and Early Childhood Home Visiting Program, the Ryan White HIV/Aids program, and Health Tomorrows Partnership for Children program. HRSA also offers training programs related to pregnancy and lactation for health care professionals. DoD provides health care services to pregnant and lactating women through TRICARE—the health care system for active duty military, dependents, and retirees. DoD also offers special programs related to pregnancy and lactation like the Family Advocacy Program and the New Parent Support Program (NPSP). VA offers health care services directly to pregnant and lactating women veterans through the Veteran's Health Administration (VHA) and in the community. In addition to primary care services, the VA offers guidance for pregnant and lactating women and their physicians about medication use during pregnancy. Two examples include VA's Pharmacy Benefit program, which bases decision aids on information from NLM's LactMed and FDA, and VA's Teratogenic Drugs Project.

Communications

As shown in Figure 6, several federal agencies fund and develop public health campaigns related to pregnant and lactating women. NIH supports Mom's Mental Health Matters campaign, which targets depression and anxiety around pregnancy. NIH also supports the Safe to Sleep campaign, which focuses on Sudden Infant Death Syndrome and other sleep-related causes of infant death, and includes information on breastfeeding. Treating for Two is an initiative by the CDC, in collaboration with federal and nonfederal partners, to improve the health of women and infants by working to find the safest treatment for common conditions before and during pregnancy. It intends to fill knowledge gaps and provide reliable guidance. The NIH-funded LactMed database is a unique resource for lactating women and their healthcare providers. It is a searchable



database to provide information on drugs and other chemicals to which breastfeeding mothers may be exposed. The Text4baby campaign, a public-private partnership involving several agencies, provides a free text messaging service with health information specifically designed for pregnant women and new mothers.

Each federal agency develops and provides health communications related to pregnancy, breastfeeding, and lactation in different forms of media. Most of these informative tools are designed to increase awareness and educate health professionals, pregnant women, mothers, and their loved ones. Many NIH ICs provide resources to the public about pregnancy and breastfeeding as it pertains to pre-existing medical conditions. VA offers information about medication use by pregnant and lactating women. OASH also provides resources about medications in pregnancy, Zika and pregnancy, tobacco and pregnancy, nursing moms in the workforce, and other information regarding breastfeeding and lactation.

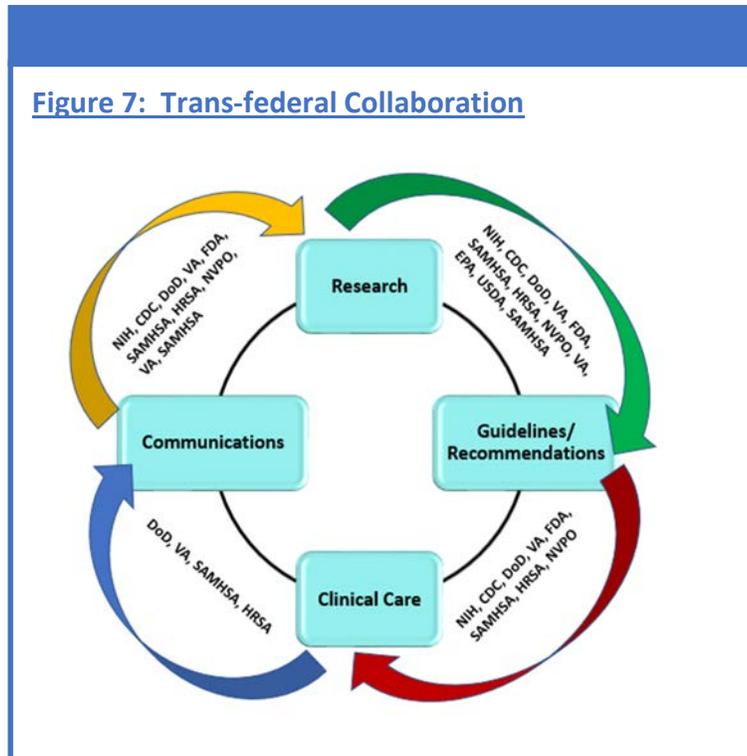
In addition to providing resources for women who are pregnant, lactating, or breastfeeding, several agencies create communication tools for health care providers as well. AHRQ gears most communication tools towards providers and health service organizations; however, it also offers fact sheets and infographics for the public about topics like substance abuse on pregnant women and infants.

DoD websites provide resources for pregnant and lactating women and their health care providers. Most of CDC communications are also designed for both public health professionals and the public. CDC develops messaging to address several medical conditions and health issues as related to pregnancy. Examples include gestational diabetes, Zika, infections, folic acid, preventing birth defects, safe medication use in pregnancy, safe medication in pregnancy, pregnancy and opioid pain medication, international travel, listeriosis, blood pressure, and breastfeeding.

FDA and NVPO also provide materials about medications and vaccines during pregnancy. FDA creates print, digital, and web-based material that provides safety information about biologics, medications, and medical devices for pregnant and lactating women and their health care providers. NVPO supports social media efforts,

administers the www.vaccines.org website that provides materials about vaccinations during pregnancy, and provided a webinar about vaccine safety in 2016.

Trans-Federal Collaborative Efforts



Federal agencies frequently join forces and work together on research, clinical guidelines and recommendations, clinical care, and communications to advance the development and appropriate use of medicinal therapies for pregnant and lactating women (see Figure 7). Examples include—but are certainly not limited to—the Federal Interagency Forum on Child and Family Statistics (NIH, HRSA, AHRQ, CDC, DoD, etc.), Treating for Two initiative (CDC and NIH), Text4Baby (NIH, HRSA, CDC, and others), antiretroviral pregnancy registry (NIH, CDC, FDA, HRSA), Zika Experimental Science Team (ZEST) (NIH, FDA, HRSA), the Immunization Safety Task Force (CDC, NIH, DOD, IHS, VA, FDA, and DoD), a conference to address opioid misuse and pregnancy (FDA, NIH, DoD, CDC, and SAMHSA), a scientific conference about children exposed to ZIKV in the womb (NIH, HRSA, EPA, USAID, and other HHS divisions), and collaborations on clinical practice guidelines (VA and DoD). The Zika

Pregnancy and Birth Defects Task Force, created by CDC in collaboration with other agencies, conducts research to reduce the impact and risk of Zika in pregnant women, infants, and children and produces data to inform stakeholders in clinical care settings.